

September 18, 2019

Robert Gibbens, D.V.M.
Director, Animal Welfare Operations
USDA/APHIS/Animal Care
2150 Centre Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Dear Dr. Gibbens:

## Research & Innovation Office

tel 503 494-1083 fax 503 494-1099

Dana Director, PhD Vice President of Research Administration & Senior Staff Officer

<u>director@ohsu.edu</u> www.ohsu.edu/research

Mail code: L335 3181 S.W. Sam Jackson Park Rd. Portland, OR 97239-3098

The Oregon Health & Science University (OHSU; 92-R-0001) provides this full explanation regarding the suspension of animal activities of two protocols by the Central and Waterfront Campus (CWC) Institutional Animal Care and Use Committee (IACUC). A unanimous vote of the quorum present at the June 12, 2019 meeting of the OHSU CWC IACUC suspended animal activities covered by two animal use protocols (IP211; IP1561) held by a single investigator. The research investigates neurophysiological processing of sound in awake behaving marmosets (IP211) and auditory brain function and plasticity in ferrets, gerbils and mice (IP1561). The suspension was reported to USDA/APHIS/AC on July 2, 2019.

The suspensions were in response to non-compliant items related to protocol IP1561. There were no non-compliant items associated with protocol IP211, however the IACUC suspended both protocols comprising all animal work under the direction of the Principal Investigator (PI).

Specific non-compliant items included conduct of a surgery using poor sterile technique; use of materials and methods for euthanasia that were not on the approved protocol; failure to document training of laboratory staff; failure to assure staff compliance with occupational health requirements; use of containers that could not be adequately sterilized to store surgical dressing supplies; failure to notify veterinary staff of animal health issues as required in the approved protocol; and failure to maintain required veterinary medical records. The CWC IACUC determined these events collectively indicated inadequate oversight of the animal care and use program by the PI in the PI's laboratory and noncompliance with PHS Policy and the Animal Welfare Act and Regulations.

Upon suspension, the Department of Comparative Medicine (DCM), directed by the Attending Veterinarian for the CWC, assumed responsibilities for care of the ferrets, gerbils and mice immediately. Daily husbandry for the marmosets was assigned to an experienced laboratory member following consultation with the Attending Veterinarian and careful consideration for the best interests of the animals. All other laboratory personnel were denied access to the animal housing facilities.

The Institutional Official was informed immediately of the suspension and the PI was provided prompt written notification. The OHSU Office of Proposal and Award Management (OPAM) informed the funding agencies of the suspensions on June 27, 2019.

The IACUC notified the PI of corrections needed in order for the status of the two protocols to be reconsidered including:

- 1. Complete correction of all non-compliant items identified in the notice of suspension; and
- 2. Development and full implementation of a plan assuring proper control and oversight of the animal program by the PI in the PI's laboratory, such that appropriate standards for the care and use of animals as research subjects will be achieved and maintained on a continuing basis.

The PI recognized his responsibility for proper control and oversight of animal care and use in the laboratory, developed a correction plan and presented it to a convened meeting of the IACUC for consideration on July 17, 2019. The plan assured that:

- 1. DCM veterinarians will continue to have full access to all animals at all times.
- 2. All IACUC-approved protocols will be reviewed annually by laboratory personnel.
- 3. Standard operating procedures (SOPs) will be developed for observation of animal health and behavior, and post-procedural care. Veterinary consultation and approval of SOPs is required.
- 4. Oversight of animal care and use in the laboratory will be facilitated by the Research Assistant functioning as laboratory manager (hired June 17, 2019) who meets weekly with the PI and is responsible for monitoring daily animal care and use by management of the following activities and maintenance of related documentation:
  - a. weekly animal health checks with veterinary staff;
  - b. assuring compliance with approved SOPs for animal related activities;
  - c. training of staff in animal care and use;
  - d. maintaining surgical and procedural records;
  - e. assuring compliance with occupational health program requirements; and
  - f. maintaining an on-line calendar which is available to DCM veterinary staff and IACUC members that details planned animal activities and training sessions.
- 5. All laboratory members will sign a laboratory agreement indicating their understanding of the responsibilities for using animal models and stressing the importance of reporting animal health and welfare concerns.
- 6. Continuing education in animal welfare will be provided monthly by the senior faculty mentor for laboratory personnel and the PI. The IACUC, IACUC office staff and DCM veterinarians are also invited.
- 7. Signage will be posted prominently requiring staff to report potential animal health or compliance concerns.
- 8. Training including IACUC 101 and IACUC 201 will be completed by the PI.
- 9. Supplemental training through the AALAS Learning Library will be completed by the Research Assistant.

Additionally, the PI will provide a written report to the IACUC on a monthly basis for at least six months documenting the activities described above. The monthly report will include details of any unexpected outcomes and continued reporting may be required beyond the six-month period.

The plan of correction was approved by the IACUC and both protocols were reinstated via unanimous vote of the IACUC. The PI and laboratory staff were permitted access to the animal facilities on July 20, 2019.

All direct costs paid from NIH Grant 5RO1DCO14950-04 and USAMRMC Award D15AP00101that were associated with the care, housing and use of the animals during the non-compliant events were removed from these accounts and invoiced to and paid from a nonfederal source.

OHSU is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by USDA/APHIS/AC. Should you have any questions regarding this report, please contact Vickie Jarrell, Ph.D., Director, Animal Care and Use Program, Office of Research Integrity.

Sincerely,

Dana Director, Ph.D.

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Vice President of Research Administration &

Senior Staff Officer

**Institutional Official** 

Oregon Health & Science University

cc: IACUC Chair

Attending Veterinarian

Director, Animal Care and Use Program